IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Daljit S. OHBI et al.	Confirmation No: 5192
Appl. No.	: 10/507,214	
Filed	: September 16, 2004	
Title	: SEAL MATERIAL FOR A DISPENSING APPARATUS	
TC/A.U.	: 1772	
Examiner	: B.T. O'Hern	
Docket No.:	: OHBI3001/REF	
Customer No:	: 23364	

37 CFR §41.37 APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief on appeal for this application is submitted with a Petition for a Two Month extension of time and the required fee extending the period for submitting the brief to February 20, 2010. The required appeal fee set forth in §41.20(b)(2) of $540 is also submitted herewith. Any additional fees necessary for this appeal may be charged to Deposit Account No. 02-0200.

41.37 (c)(1)(I) REAL PARTY IN INTEREST

The real party in interest is the Assignee of record, CONSORT MEDICAL PLC.

41.37 (c)(1)(ii) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences with respect to the claimed invention which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal known to appellant, appellant's legal representative or assignee.

41.37 (c)(1)(iii) STATUS OF THE CLAIMS

This application contains claims 1-41. Claims 21 and 28-36 have been canceled from the application without prejudice or disclaimer and are no longer pending. Claims 1-20, 22-27 and 37-41 are pending and stand finally rejected under 35 USC 103(a) as obvious over the prior art cited and applied in the Final Rejection.

41.37 (c)(1)(iv) STATUS OF AMENDMENTS AFTER FINAL REJECTION

No amendment was filed after Final Rejection. A notice of appeal was filed in response to the Final Rejection.

41.37 (c)(1)(v) SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 relates to a pharmaceutical dispensing device valve seal which is a vulcanisate of an elastomeric composition comprising: (page 6, line 8, page 12, lines 21-29)

(a) an isobutylene polymer or co-polymer thereof; (page 4, lines 20,21)

(b) a cross-linking agent for the isobutylene polymer or co-polymer thereof, wherein the cross-linking agent is sulphur or a sulphur-donating compound, (page 4, line 23, page 8, lines 27,28) and wherein the cross-linking agent is free of peroxide curing agents; and

(c) an accelerator for the cross-linking agent, wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof. (Page 13, lines 12-14)

Claim 5 claims a pharmaceutical dispensing device valve seal which is a vulcanisate of an elastomeric composition comprising: (page 6, line 8, page 12, lines 21-29)

(a) a chlorine-substituted diene polymer or co-polymer thereof; (page 5, lines 25, 26)

(b) a cross-linking agent for the chlorine-substituted diene polymer or co-polymer thereof, wherein the cross-linking agent is sulphur or a sulphur-donating compound, and wherein the cross-linking agent is free of peroxide curing agents; and

(c) an accelerator for the cross-linking agent, wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof. (Page 5, lines 27-30)

Claim 6 claims a seal as claimed in claim 5, wherein the elastomeric composition comprises a chlorine-substituted butadiene polymer and claim 7 claims a seal as

claimed in claim 6, wherein the elastomeric composition comprises 2-chlorobuta-1,3-diene. (Page 5, lines 33-35)

Claim 10 claims a seal as claimed in claim 1, wherein said polysulphide compound is diisopropyl xanthogen polysulphide (page 5, lines 8-10); and claim 11 claims a seal as claimed in claim 1, wherein said polysulphide compound comprises three or more bridging sulphur atoms. (Page 9, lines 1-3)

Claim 40 claims a pharmaceutical dispensing device which has a valve having a seal as claimed in claim 1 and which device is a pharmaceutical metered dose aerosol inhaler device (page 6, line 11) containing a hydrofluorocarbon propellant comprising propellant type 134a or 227.

Claim 41 claims a pharmaceutical dispensing device which has a valve having a seal as claimed in claim 5 and which device is a pharmaceutical metered dose aerosol inhaler device (page 6, line 11) containing a hydrofluorocarbon propellant comprising propellant type 134a or 227.

41.37 (c)(1)(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

THE OBVIOUSNESS REJECTIONS

A. Whether the rejection of claims 1-6, 8-9, 12-20, 22-27 and 37-41 under 35 USC 103(a) as unpatentable over Chan et al., WO 02/072449, in view of Kaszas et al and Whitby renders the claims prima facie obvious.

B. Whether the rejection of claim 7 under 35 USC 103(a) as unpatentable over Chan et al., in view of Whitby, Kaszas et al and Simmons et al renders claim 7 prima facie obvious.

C. Whether the rejection of claim 10 under 35 USC 103(a) as unpatentable over Chan et al., in view of Whitby, Kaszas et al and Stevenson et al renders claim 10 prima facie obvious.

D. Whether the rejection of claim 11 under 35 USC 103(a) as unpatentable over Chan et al., in view of Whitby, Kaszas et al and Blok et al. renders claim 11 prima facie obvious.

41.37 (c)(1)(viii) ARGUMENT

THE OBVIOUSNESS REJECTIONS

Examples Of Basic Requirements of a Prima Facies Case of Obviousness

The appellant submits that the criteria set forth in the MPEP provides guidance in determining the issue of obviousness of the claims on appeal.

---SECTION---2143 Examples Of Basic Requirements of a Prima Facie Case of Obviousness

The Supreme Court in KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in Graham. The key to supporting any rejection under 35

U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. (Emphasis added.)

SECTION---2143.03 All Claim Limitations Must Be Taught or Suggested

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Appellants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-130) wherein it is stated that Office personnel should consider all rebuttal argument and evidence present by applicant and the citation of In re Soni for error in not considering evidence presented in the specification.

THE FIRST OBVIOUSNESS REJECTION

A. The first obvious rejection to be reviewed is of claims 1-6, 8-9, 12-20, 22-27 and 37-41 under 35 USC 103(a) as unpatentable over Chan et al., WO 02/072449, in view of Kaszas et al and Whitby which combination does not render the claims prima facie obvious

WO 02/072449 is concerned with a canister suitable for use in metered dose inhalers and fitted with a metering valve characterized in that its walls are formed of a laminate comprising a first layer which is composed of a metal and a second layer which is composed of a strengthening material. The citation is therefore concerned with improving the mechanical properties of the walls of the canister by using a laminated material. This has nothing to do with the presently claimed invention which is directed

to reducing the formation of nitrosamines in SEALS for a pharmaceutical dispensing apparatus. It is interesting to note that the assignee of the present application, Bespak plc.,(named changed to Consort Medical PLC) is identified as a supplier of commercially available suitable metering valves for the canister of the invention of the '449 application. This is set forth at the bottom of page 11 of the '499 application which just proceeds the citation relied upon in the discussion of the primary reference in the rejection, see page 3 of the rejection where pages 12 to 13 are cited.

Clearly, the cited pages relate to the prior art compositions which fail to suggest the presently claimed invention as admitted on page 3 of the Final Rejection which states that the primary reference fails to expressly disclose a cross-linking agents such as sulfur or a sulfur donating compound free of peroxide curing agents and a polysulphide accelerator derived from xanthic acid or a derivative thereof having an isopropyl group, with the polysulfphide being substantially free from nitrogen, phosphorous and metallic elements, wherein the elastomeric composition comprises up to 3 wt.% (1.5wt%) of the accelerator based on the total weight of the accelerator and polymer in the composition wherein the weight ratio of the accelerator to the cross-linking agent in the elastomeric composition is in the range of from 1:1 to 3:1 which forms part of the presently claimed invention.

Moreover, the preceding statement in the Final Rejection that Chan teaches "...a valve body defining a chamber, and a valve member extending through the chamber with at least one annular seal cooperating with the valve members wherein the seal is comprises an isobutylene polymer or co-polymer, butyl rubber, neoprene (poly-chloroprene) chloro-butyl rubbers etc.." is not found in the reference. The presently claimed invention relates to a specific type of elastomer in combination with a specific curing system. In claim 1, the elastomer is an isobutylene polymer or co-polymer and in claim 5, it is a chlorine-substituted diene polymer or co-polymer thereof in combination with the curing component and this combination is not suggested in the prior art. If this argument is continued to be relied upon in the rejection, further

clarification is requested for support for this conclusion which appears to be based on improper hindsight from Applicants' disclosure.

There is no suggestion of the problem in the primary reference and even under KSR, Applicants' specification may not be used as a teaching reference. As noted at page 16 of Applicants' specification, in the seal compositions according to the present invention the accelerator is typically almost totally consumed during the cross-linking reaction. This results in a cleaner rubber and the extractables are reduced. Typically, substantially no nitrosamines are generated during the cross-linking reaction. Furthermore, the composition according to the present invention show improved ageing characteristics compared with the convention Neoprene and Butyl rubber formulations. Most or substantially all of any by products resulting from the cross-linking reaction may be volatiles.

However, the primary reference does recognize that it is preferable to manufacture the seals out of a material which is inert to and resists extraction into the contents of the formulation, especially when the contents contain ethanol. See page 12, lines 15-18 of the primary reference.

The statement of claim interpretation at the top of page 3 of the Final Rejection is not understood and clarification is requested. It does not appear to be factual accurate. It is stated that Applicants' invention is interpreted as being a dispensing device and not including material inside the device. However, at least claims 22, 25-27 and 37-41 are to a device containing contents which is a claim limitation which cannot be ignored. Clarification is most respectfully requested.

As previously noted, Applicants most respectfully submit that it is clear that the claims are directed to seal for a valve for a pharmaceutical dispensing device which includes metered dose inhalers which must meet strict FDA standards to insure proper operation and free of contamination. Such contamination may come from the seals used in these devices. On the contrary, Kaszas relates to tire inner tubes, air bladders and the like. At column 9, lines 50-55 the use of the vulcanizate as an aerosol spray can linings is described but this is not a seal for a valve as presently claimed or a device

containing such a valve. In an effort to overcome the deficiencies, the Final Rejection, at page 3, states that Kaszas teaches aerosol dispensers with polymeric barrier material and that seals are barriers. This is not believed to be a reasonable interpretation of the Kaszas reference by one of ordinary skill in the art and clearly relies on Applicants' disclosure. Even under KSR, Applicants' specification may not be used as a teaching reference. Moreover, one of ordinary skill in the art would appreciate that aerosol spray can linings do not suggest the use of the compositions of Kaszas for valve seals in a pharmaceutical containing aerosol which are subject to higher standards. An aerosol spray can for paint is completely different than a metered dose inhaler as would be appreciated by one of ordinary skill in the art. This is especially true in view of the results achieved by the present invention as evidence by the tablulation and examples in Applicants' specification.

Moreover, an important aspect of the invention is the curing system to produce the claimed vulcanisate which includes the following limitations:

As a cross-linking agent:	*sulphur or a sulphur-donating compound, the cross-linking agent being free of peroxide curing agents.*
As an accelerator:	*a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.*

More specifically, Kaszas relates to butyl elastomeric compositions for use in articles requiring low or reduced permeability to gases and improved tear strength, such as tire inner tubes, tire curing bladders and various air bladders (see column 1, lines 6 to 31). The curing system is discussed in column 8, lines 1 to 4, and comprises (I) metal oxide, (ii) sulphur, and (iii) at least one sulphur-based accelerator. Kaszas discloses the following accelerators: thiuram sulphides such as tetramethyl thiuram disulphide (TMTD), thiocarbamates such as zinc dimethyl thiocarbamates (ZDC) and the thiazyl and benzothiazyl compounds such as mercaptobenzothiazyl disulphide (MBTS) (see column 8, lines 10 to 18). The preferred accelerator is said to be

tetramethyl thiuram disulphide (TMTD) (see also column 14, Table VI). The present application acknowledges the use of these known accelerators (see page 2 of the specification, lines 26-35).

As discussed on pages 3 and 4 of the of the present application, it has been found that tetramethyl thiuram disulphide (TMTD) (and also mercaptobenzothiazyl disulphide (MBTS)) is a precursor for the formation of nitrosamines, which are undesirable in seals for pharmaceutical dispensing devices. Thus, the use of these compounds in a curing system for use in the manufacture of a seal for a pharmaceutical dispenser device has this disadvantage (of course, there is no appreciation of this disadvantage in Kaszas since this document is not concerned with pharmaceutical dispenser devices). Furthermore, in most pharmaceutical applications, it is also necessary to extract or wash the cured elastomer in order to remove surface residues and by-products resulting from the cure reaction and moulding process. The aforementioned conventional cure/accelerator systems require relatively lengthy extraction times (typically 50 to 70 hours). Prolonged extraction times have been found to result in a deterioration in material properties.

The present invention solves these problems by the use of a cross-linking system in which:

sulphur or a sulphur-donating compound is used as a cross-linking agent (the cross-linking agent being free of peroxide curing agents), and

a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof is used as an accelerator.

It is submitted that there is no teaching or suggestion of such a system in Kaszas. In particular, there is no mention in Kaszas of an accelerator which is a polysulphide compound derived from a substituted dithiocarbonic acid such as xanthic acid. While Kaszas does mention dithiocarbamate compounds, these are salts of dithiocarbamic acid, i.e. NH_2CS_2H. Indeed, the present application acknowledges such accelerators on page 2, line 28 of the description. As will be appreciated, dithiocarbamic acid (NH_2CS_2H) is quite different from dithiocarbonic acid (carbonic acid

is H_2CO_3) and Kaszas is silent regarding polysulphide compounds derived from a substituted dithiocarbonic acid, for example diisopropyl xanthogen polysulphide.

Moreover, the Final Rejection urges that Kaszas teaches that the cross-linking agent is free of peroxide curing agents. While there is no indication in the reference that peroxides are present, the reference does indicate that the curing system is not particularly restricted and there is no particular exclusion of peroxide as a requirement of the curing system as recited in the claims on appeal. Again, this statement appears to be based on Applicants' teaching and not the teachings of Kaszas. For the sake of completeness it is also pointed out that there is no mention in Kaszas of a seal for a valve for a pharmaceutical dispensing device (notwithstanding that the crosslinking system recited in the claims of the present application is neither taught nor suggested by Kaszas). Furthermore, Kaszas is not concerned with a valve for use in a pharmaceutical dispensing device (as claimed in claim 20), or a pharmaceutical dispensing device (as claimed in claims 21 and 22), or a dispensing apparatus for dispensing pressurised fluid (as claimed in claims 23 to 27). Contrary to the assertion at the top of page 4 of the Final Rejection, there is nothing in Kaszas which suggests the formation of a strong seal with very low permeability at column 2, lines 36-42 of the reference. Again, this interpretation is based on Applicants' disclosure which is improper hindsight.

In the Final Rejection, it is urged that Whitby teaches providing accelerators for the vulcanization of rubber such as polysulphides substituted dithiocarbonic acid or derivatives thereof such as xanthic acids having isopropyl groups with sulfur for the purpose of providing a rubber product with better properties that can be prepared at lower temperatures. At the outset, Applicants wish to note that this is a 1927 patent which is to provide a new and improved class of accelerators for the vulcanization of rubber which will give to the finished rubber product excellent physical properties, high tensile strength, rapidity of the vulcanization at lower temperatures and related properties.

As stated at page 2, line 28 et seq of the patent, these products when incorporated into a rubber mix, especially when an amine of the aniline type is also present, greatly accelerate the vulcanization of rubber, increase the tensile strength of the rubber and impart other desirable qualities. Example I shows that this product of the invention is mixed with 100 parts by weight of smoked sheet which is a rubber and clearly, there is no suggestion in this reference in using the accelerator to form a vulcanisate to form a valve seal in accordance with the presently claimed invention. This is particularly true in view of the results achieved by the presently claimed invention as evidenced by the data contained in the present specification, see for example page 16 and the figures demonstrating the unique combination of properties exhibited by the presently claimed invention as noted above.

The curing system described in Kaszas includes a metal oxide, an elemental sulfur compound and thiuram sluphide. There is nothing to suggest using the xanthates of Whitby in the Kaszas system which clearly prefers tetramethyl thiuram disulphide. Again such a substitution appears to be based on Applicants' teaching which represents improper hindsight. Once again, Applicants' specification may not be used as a teaching reference to arrive at the presently claimed invention and ignoring the teachings of the reference, as a whole, including those portions which lead away from the claimed invention.

Applicants also most respectfully direct the Examiner's attention to MPEP § 2145 wherein it is stated that Office personnel should consider all rebuttal argument and evidence presented by applicant and the citation of In re Soni for error in not considering evidence presented in the specification. Accordingly, it is most respectfully requested that this rejection be withdrawn.

A-1 Claim 40 claims a pharmaceutical dispensing device which has a valve having a seal as claimed in claim 1 and which device is a pharmaceutical metered dose aerosol inhaler device containing a hydrofluorocarbon propellant comprising propellant type 134a or 227. All of the limitations contained in this claim must be considered in

determining the patentability of the claimed subject matter. In this regard, see the comments in the Final Rejection on page 3 which suggest that these limitations have been ignored. Metered Dose Inhalers (MDI) need to meet specific requirements and standards set by the FDA. As clearly set forth in Applicants' specification, see pages 28 and 29, the MDI of the invention possess a unique combination of properties which are believed attributable to the curing system of the claimed invention and not shown by the prior art. Accordingly, this aspect of the rejection should be withdrawn or reversed on appeal.

A-2 Claim 41 claims a pharmaceutical dispensing device which has a valve having a seal as claimed in claim 5 and which device is a pharmaceutical metered dose aerosol inhaler device (page 6, line 11) containing a hydrofluorocarbon propellant comprising propellant type 134a or 227. All of the limitations contained in this claim must be considered in determining the patentability of the claimed subject matter. Metered Dose Inhalers (MDI) need to meet specific requirements and standards. As clearly set forth in Applicants' specification, see pages 28 and 29, the MDI of the invention possess a unique combination of properties not shown by the prior art. Accordingly, this aspect of the rejection should be withdrawn or reversed on appeal.

THE SECOND OBVIOUSNESS REJECTION

B. The second obvious rejection to be reviewed is of whether the rejection of claim 7 under 35 USC 103(a) as unpatentable over Chan et al., in view of Whitby, Kaszas et al and Simons et al renders claim 7 prima facie obvious.

The rejection of claim 7 under 35 U.S.C. 103(a) is based on the combination of references of Chan et al, Whitby and Kaszas et al. with respect to the first obviousness rejection and for the above reasons, the first combination of references does not render the claimed invention prima facie obvious. Simons et al. has been carefully considered but does overcome the deficiencies of the first combination of references. In order to combine the references, the teachings of the reference as a whole must be taken into consideration. For example, Kaszas do not teach the valve seal of the invention and the teachings of the Simons reference does not overcome these deficiencies.

Simons relates to a method of making gasketed closure elements for pressurized aerosol containers. This is an unrelated technical field to Kaszas, which is concerned with articles requiring low or reduced permeability to gases and improved tear strength, such as tire inner tubes, tire curing bladders and various air bladders. There would therefore be no motivation for one skilled in the art to combine these references. Simons is also not concerned with seals/valves for use in a pharmaceutical dispensing device. Moreover, clarification is requested as to where in the reference, Simons, teaches an elastomeric composition comprising a chlorine-substituted butadiene polymeric 2-chlorobuta-1, 3-diene. This is clearly not taught in the sections referred to in the rejection. Accordingly, it is most respectfully requested that this rejection be withdrawn.

THE THIRD OBVIOUSNESS REJECTION

C. The rejection of claim 10 under 35 USC 103(a) as unpatentable over Chan et al., in view of Whitby, Kaszas et al and Stevenson et al renders claim 10 does not render claim 10 prima facie obvious.

The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Chan et al, in view of Whitby, Kaszas et al. and Stevenson et al. has been carefully considered but is most respectfully traversed in view of the above comments as applied to the previously cited references and the following comments.

Stevenson relates to an article such as an automobile component, for example, a tire. An aircraft tire is specifically mentioned, among others. Stevenson is plainly not concerned with seals and valves for use in a pharmaceutical dispensing device. Stevenson does describe diisopropyl xanthogen polysulphide as an accelerator in rubber curing processes. Even if this accelerator where used in the Chan invention as urged in the rejection, the presently claimed valve seal would not be achieved because the combination of cross linking agent and accelerator would not be used. This is especially true in view of the results achieved and as illustrated in the Tables in the present application. There would therefore be no motivation for one skilled in the art to look to this reference when faced with the present invention and therefore it is most respectfully requested that this rejection be withdrawn or reversed on appeal.

THE FOURTH OBVIOUSNESS REJECTION

D. The rejection of claim 11 under 35 USC 103(a) as unpatentable over Chan et al., in view of Whitby, Kaszas et al and Blok et al. does not render claim 11 prima facie obvious for the reasons discussed above.

Blok relates to EPDM and EPR-based rubber compositions which are vulcanized with peroxide together with a specified combination of sulfur and acrylate co-agents. However, a requirement of claim 1 on appeal is that the cross-linking agent is free of peroxide curing agents. This means that Blok teaches away from the present invention and cannot render the claims obvious. Accordingly, it is most respectfully requested that this rejection be withdrawn.

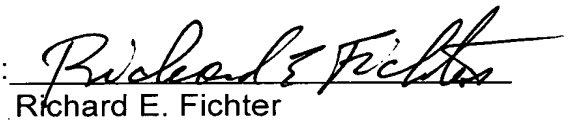
This is the same argument as previously presented to which the Examiner responded in the Final Rejection, paragraph 15, in which it is stated that Blok is cited for teaching claim 11 and not claim 1. However, claim 11 is dependent on claim 1 and therefore contains all of the limitations of claim 1 contrary to the assertion in the Final Rejection.

IX. CONCLUSION

In view of the above arguments, all of the rejections of the claims on appeal should be reversed. The application should be passed to issue.

Respectfully submitted,

BACON & THOMAS, PLLC

By: 

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41.37 (c)(1)(viii) Claims appendix

1. A pharmaceutical dispensing device valve seal which is a vulcanisate of an elastomeric composition comprising:

(a) an isobutylene polymer or co-polymer thereof;

(b) a cross-linking agent for the isobutylene polymer or co-polymer thereof, wherein the cross-linking agent is sulphur or a sulphur-donating compound, and wherein the cross-linking agent is free of peroxide curing agents; and

(c) an accelerator for the cross-linking agent, wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.

2. A seal as claimed in claim 1, wherein the elastomeric composition comprises one or more of polyisobutylene, polybutene, butyl rubber, halogenated butyl rubber.

3. A seal as claimed in claim 2, wherein the elastomeric composition comprises bromobutyl rubber and/or chlorobutyl rubber.

4. A seal as claimed in claim 1, wherein the elastomeric composition comprises a blend of an isobutylene polymer or co-polymer thereof and a chlorine-substituted diene polymer or co-polymer thereof.

5. A pharmaceutical dispensing device valve seal which is a vulcanisate of an elastomeric composition comprising:

(a) a chlorine-substituted diene polymer or co-polymer thereof;

(b) a cross-linking agent for the chlorine-substituted diene polymer or co-polymer thereof, wherein the cross-linking agent is sulphur or a sulphur-donating compound, and wherein the cross-linking agent is free of peroxide curing agents; and

(c) an accelerator for the cross-linking agent, wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.

6. A seal as claimed in claim 5, wherein the elastomeric composition comprises a chlorine-substituted butadiene polymer.

7. A seal as claimed in claim 6, wherein the elastomeric composition comprises 2-chlorobuta-1,3-diene.

8. A seal as claimed in claim 1, wherein said polysulphide compound is derived from a substituted xanthic acid or derivative thereof.

9. A seal as claimed in claim 1, wherein the substituted group in said polysulphide compound is an isopropyl group. .

10. A seal as claimed in claim 1, wherein said polysulphide compound is diisopropyl xanthogen polysulphide.

11. A seal as claimed in claim 1, wherein said polysulphide compound comprises three or more bridging sulphur atoms.

12. A seal as claimed in claim 1, wherein said polysulphide compound is substantially free from nitrogen, phosphorus and metallic elements.

13. A seal as claimed in claim 1, wherein the elastomeric composition comprises up to 3 wt.% of the accelerator based on the total weight of the accelerator and polymer in the composition.

14. A seal as claimed in claim 13, wherein the elastomeric composition comprises up to 1.5 wt.% of the accelerator based on the total weight of the accelerator and polymer in the composition.

15. A seal as claimed in claim 1, wherein the weight ratio of the accelerator to the cross-linking agent in the elastomeric composition is in the range of from 1:1 to 3:1.

16. A seal as claimed in claim 1, wherein the seal further includes a mineral filler.

17. A seal as claimed in claim 16, wherein the mineral filler is selected from one or more of magnesium silicate, aluminum silicate, silica, titanium oxide, zinc oxide, calcium carbonate, magnesium oxide magnesium carbonate, magnesium aluminum silicate, aluminum hydroxide, talc, kaolin, clay and amino silane coated clay.

18. A seal as claimed in claim 1, wherein the seal further includes a process aid a low molecular weight polyethylene.

19. A seal as claimed in claim 1, further comprising one or more of a reinforcement agent, a plasticizer, a binder, a stabilizer, a retarder, a bonding agents, an antioxidant, a lubricant, a pigment, a wax, a resin, an antiozonants, a secondary accelerator or an activator.

20. A pharmaceutical dispensing device containing a valve having a seal as defined in claim 1.

22. A pharmaceutical dispensing device as claimed in claim 20 which is a pharmaceutical metered dose aerosol inhaler device.

23. A dispensing apparatus for dispensing pressurised fluid comprising a valve body defining a chamber, a valve member extending movably through the chamber and through at least one annular seal cooperating with the valve member and the body to regulate the discharge of fluid, wherein the at least one of the seals is as defined in claim 1.

24. A dispensing apparatus which comprises a pressurised dispensing container having a valve body provided with two annular valve seals through which a valve member is axially slidable, said seals being disposed at inlet and outlet apertures of a valve chamber so that the valve functions as a metering valve, wherein at least one of the annular valve seals is as defined in claim 1.

25. A dispensing apparatus as claimed in claim 23, comprising a pressurised dispensing container operatively connected to the valve body and containing the fluid to be dispensed and a hydrofluorocarbon propellant comprising propellant type 134a or 227.

26. A dispensing apparatus as claimed in clam 23, wherein the fluid to be dispensed comprises a liquid or particulate product as a solution or suspension in a carrier liquid comprising alcohol.

27. A dispensing apparatus as claimed in claim 26, wherein the alcohol comprises ethanol.

37. A pharmaceutical dispensing device as claimed in claim 20 which is a pharmaceutical metered dose aerosol inhaler.

38. A pharmaceutical dispensing device containing a valve having a seal as defined in claim 5.

39. A pharmaceutical dispensing device as claimed in claim 38 which is a pharmaceutical metered dose aerosol inhaler.

40. A pharmaceutical dispensing device as claimed in claim 37 and containing a hydrofluorocarbon propellant comprising propellant type 134a or 227.

41. A pharmaceutical dispensing device as claimed in claim 39 and containing a hydrofluorocarbon propellant comprising propellant type 134a or 227.

41.37 (c)(1)(ix) Evidence appendix

None

41.37 (c)(1)(x) Related proceedings appendix

None